

HEALTHCARE COMMON PROCEDURE CODING SYSTEM (HCPCS) LEVEL II CODING PROCEDURES

This information provides a description of the procedures CMS follows in making coding decisions.

FOR FURTHER INFORMATION CONTACT:

Gloria Knight (410) 786-4598, Felicia Eggleston (410) 786-9287, Jennifer Carver (410) 786-6610, Trish Brooks (410) 786-4561, or Cindy Hake (410) 786-3404 for HCPCS level II coding issues.

A. HCPCS BACKGROUND INFORMATION

Each year, in the United States, health care insurers process over 5 billion claims for payment. For Medicare and other health insurance programs to ensure that these claims are processed in an orderly and consistent manner, standardized coding systems are essential. The HCPCS Level II Code Set is one of the standard code sets used for this purpose. The HCPCS is divided into two principal subsystems, referred to as level I and level II of the HCPCS. Level I of the HCPCS is comprised of CPT (Current Procedural Terminology), a numeric coding system maintained by the American Medical Association (AMA). The CPT is a uniform coding system consisting of descriptive terms and identifying codes that are used primarily to identify medical services and procedures furnished by physicians and other health care professionals. These health care professionals use the CPT to identify services and procedures for which they bill public or private health insurance programs. Decisions regarding the addition, deletion, or revision of CPT codes are made by the AMA. The CPT codes are republished and updated annually by the AMA. Level I of the HCPCS, the CPT codes, does not include codes needed to separately report medical items or services that are regularly billed by suppliers other than physicians.

Level II of the HCPCS is a standardized coding system that is used primarily to identify products, supplies, and services not included in the CPT codes, such as ambulance services and durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) when used outside a physician's office. Because Medicare and other insurers cover a variety of services, supplies, and equipment that are not identified by CPT codes, the level II HCPCS codes were established for submitting claims for these items. The development and use of level II of the HCPCS began in the 1980's. Level II codes are also referred to as alpha-numeric codes because they consist of a single alphabetical letter followed by 4 numeric digits, while CPT codes are identified using 5 numeric digits.

In October of 2003, the Secretary of HHS delegated authority under the HIPAA legislation to CMS to maintain and distribute HCPCS Level II Codes. As stated in 42 CFR Sec. 414.40 (a) CMS establishes uniform national definitions of services, codes to represent services, and payment modifiers to the codes. Within CMS there is a CMS HCPCS Workgroup which is an internal workgroup comprised of representatives of the major components of CMS, as well as other consultants from pertinent Federal agencies. Prior to December 31, 2003, Level III HCPCS were developed and used by Medicaid State agencies, Medicare contractors, and private insurers in their specific programs or local areas of jurisdiction. For purposes of Medicare, level III codes were also referred to as local codes. Local codes were established when an insurer preferred that suppliers use a local code to identify a service, for which there is no level I or level

II code, rather than use a "miscellaneous or not otherwise classified code." The Health Insurance Portability and Accountability Act of 1996 (HIPAA) required CMS to adopt standards for coding systems that are used for reporting health care transactions. We published, in the Federal Register on August 17, 2000 (65 FR 50312), regulations to implement this part of the HIPAA legislation. These regulations provided for the elimination of level III local codes by October 2002, at which time, the level I and level II code sets could be used. The elimination of local codes was postponed, as a result of section 532(a) of BIPA, which continued the use of local codes through December 31, 2003.

B. HCPCS LEVEL II CODES

The regulation that CMS published on August 17, 2000 (45 CFR 162.10002) to implement the HIPAA requirement for standardized coding systems established the HCPCS level II codes as the standardized coding system for describing and identifying health care equipment and supplies in health care transactions that are not identified by the HCPCS level I, CPT codes. The HCPCS level II coding system was selected as the standardized coding system because of its wide acceptance among both public and private insurers. Public and private insurers were required to be in compliance with the August 2000 regulation by October 1, 2002. The purpose of this section is to provide a general description of the current HCPCS level II coding system.

The HCPCS level II coding system is a comprehensive and standardized system that classifies similar products that are medical in nature into categories for the purpose of efficient claims processing. For each alphanumeric HCPCS code, there is descriptive terminology that identifies a category of like items. These codes are used primarily for billing purposes. For example, suppliers use HCPCS level II codes to identify items on claim forms that are being billed to a private or public health insurer.

HCPCS is a system for identifying items and services. It is not a methodology or system for making coverage or payment determinations, and the existence of a code does not, of itself, determine coverage or non-coverage for an item or service. While these codes are used for billing purposes, decisions regarding the addition, deletion, or revision of HCPCS codes are made independent of the process for making determinations regarding coverage and payment.

Currently, there are national HCPCS codes representing over 4,000 separate categories of like items or services that encompass millions of products from different manufacturers. When submitting claims, suppliers are required to use one of these codes to identify the items they are billing. The descriptor that is assigned to a code represents the definition of the items and services that can be billed using that code. To avoid any appearance of endorsement of a particular product through HCPCS, the descriptors that are used to identify codes do not refer to specific products. For this reason, brand or trade names are not used to describe the products represented by a code.

In summary, the HCPCS level II coding system has the following characteristics:

- This system ensures uniform reporting on claims forms of items or services that are medical in nature. Such a standardized coding system is needed by public and private insurance programs to ensure the uniform reporting of services on claims forms by suppliers and for meaningful data collection.

- The descriptors of the codes identify a category of like items or services rather than specific products or brand/trade names.
- The coding system is not a methodology for making coverage or payment determinations. Each payer makes determinations on coverage and payment outside this coding process.

C. TYPES OF HCPCS LEVEL II CODES

There are several types of HCPCS level II codes depending on the purpose for the codes and who is responsible for establishing and maintaining them.

Permanent National Codes

National permanent HCPCS level II codes are maintained by the CMS HCPCS Workgroup. The Workgroup is responsible for making decisions about additions, revisions, and deletions to the permanent national alpha-numeric codes. These codes are for the use of all private and public health insurers. Since HCPCS is a national coding system all payers will be represented in the Workgroup including representatives from private insurance agencies, the Statistical Analysis Durable Medical Equipment Regional Carriers (SADMERC), and Medicaid will participate in the workgroup meetings and provide input as to what is necessary to meet each party's program operating needs.

The permanent national codes serve the important function of providing a standardized coding system that is managed jointly by private and public insurers. This standardized approach to developing a set of uniform codes provides a stable environment for claims submission and processing.

Dental Codes

The dental codes are a separate category of national codes. The Current Dental Terminology (CDT) is a publication copyrighted by the American Dental Association (ADA) that lists codes for billing for dental procedures and supplies. The CDT is included in HCPCS level II. Decisions regarding the revision, deletion, or addition of CDT codes are made by the ADA and not the CMS HCPCS Workgroup.

As the Department of Health and Human Services has an agreement with the AMA pertaining to the use of the Current Procedural Terminology (CPT) codes for physician services, it also has an agreement with the ADA to include CDT as a set of HCPCS level II codes for use in billing for dental services.

Miscellaneous Codes

National codes also include "miscellaneous/not otherwise classified" codes. These codes are used when a supplier is submitting a bill for an item or service and there is no existing national code that adequately describes the item or service being billed. The importance of miscellaneous codes is that they allow suppliers to begin billing immediately for a service or item as soon as it is allowed to be marketed by the Food and Drug Administration (FDA) even though there is no distinct code that describes the service or item. A miscellaneous code can be used during the period of time a request for a new code is being considered under the HCPCS review process. The use of miscellaneous codes also helps us to avoid the inefficiency and administrative burden

of assigning distinct codes for items or services that are rarely furnished or for which we expect to receive few claims.

Because of miscellaneous codes, the absence of a specific code for a distinct category of products does not affect a supplier's ability to submit claims to private or public insurers and does not affect patient access to products. Claims with miscellaneous codes are manually reviewed, the item or service being billed must be clearly described, and pricing information must be provided along with documentation to explain why the item or service is needed by the beneficiary.

Ordinarily, before using a miscellaneous code on a claim form, a supplier should check with the entity that will receive the payment claim to determine whether there is a specific code that should be used rather than a miscellaneous code. In the case of claims that are to be submitted to one of the four durable medical equipment regional carriers (DMERCs), suppliers that have coding questions should check with the statistical analysis durable medical equipment carrier (SADMERC) under contract to CMS. The SADMERC is responsible for providing suppliers and manufacturers with assistance in determining which HCPCS code should be used to describe DMEPOS items for the purpose of billing Medicare. The SADMERC has a toll free helpline for this purpose, (877) 735-1326, which is operational during the hours of 9 AM to 4 PM (EST). In addition, The SADMERC publishes a product classification list on its website that lists individual items to code categories. More information about the SADMERC and the SADMERC's product classification list can be found at <http://www.palmettogba.com>.

If no code exists that describes the product category to which the item belongs, and if the item fits a Medicare Benefit Category, the SADMERC may instruct the supplier to submit claims using a "miscellaneous/not otherwise classified" code. If an item does not fit a Medicare Benefit Category, the SADMERC might assign a code that indicates that the product is not covered by Medicare for example, code A9270, NON-COVERED ITEM OR SERVICE. If an item is included or bundled into another code and not separately reimbursed by Medicare, the SADMERC may assign the code that includes the item or a code that indicates that the item is included as a component of another code. In those cases in which a supplier or manufacturer has been advised to use a miscellaneous code because there is no existing code that describes a given product, and the supplier or manufacturer believes that the code is needed, it should submit a request to modify the HCPCS in accordance with the established process. The process for requesting a revision to the HCPCS level II codes is explained below.

Temporary National Codes

Temporary codes are for the purpose of meeting, within a short time frame, the national program operational needs of a particular insurer that are not addressed by an already existing national code. The CMS HCPCS Workgroup has set aside certain sections of the HCPCS code set to allow the Workgroup to develop temporary codes. Decisions regarding the number and type of temporary codes and how they are used are also made by the CMS HCPCS Workgroup. These codes are used at the discretion of CMS. This means that if, before the next scheduled annual update for permanent codes, the CMS HCPCS Workgroup needs a code in order to meet specific operating needs that pertain to its particular programs, it may establish a national temporary code. In the case of Medicare, decisions regarding temporary codes are made by the CMS

HCPCS workgroup. For example, Medicare may need additional codes before the next scheduled annual HCPCS update to implement newly issued coverage policies or legislative requirements. Although we establish temporary codes to meet our specific operational needs, the temporary codes we establish can be used by other insurers. Temporary codes allow insurers the flexibility to establish codes that are needed before the next January 1 annual update for permanent national codes or until consensus can be achieved on a permanent national code. Permanent national codes are only updated once a year on January 1.

The CMS HCPCS Workgroup may decide to replace temporary codes with permanent codes. However, temporary codes do not have established expiration dates. Whenever a permanent code is established by the CMS HCPCS Workgroup to replace a temporary code, the temporary code is deleted and cross-referenced to the new permanent code.

Types of temporary HCPCS codes:

- The C codes were established to permit implementation of section 201 of the Balanced Budget Refinement Act of 1999. The C codes identify items that may qualify for "pass through" payments under the hospital outpatient prospective payment system (HOPPS). These codes are used exclusively for the HOPPS purposes and are only valid for Medicare on claims submitted by hospital outpatient departments. More information regarding HOPPS can be found at <http://www.cms.hhs.gov/providers/hopps/>.
- The G codes are used to identify professional health care procedures and services that would otherwise be coded in CPT-4 but for which there are no CPT-4 codes.
- The Q codes are used to identify services that would not be given a CPT-4 code, such as drugs, biologicals, and other types of medical equipment or services, and which are not identified by national level II codes but for which codes are needed for claims processing purposes.
- The K codes were established for use by the DMERCs when the currently existing permanent national codes do not include the codes needed to implement a DMERC medical review policy. For example, codes other than the permanent national codes may be needed by the DMERCs to identify certain product categories and supplies necessary for establishing appropriate regional medical review coverage policies.
- The S codes are used by private insurers to report drugs, services, and supplies for which there are no national codes but for which codes are needed by the private sector to implement policies, programs, or claims processing. They are for the purpose of meeting the particular needs of the private sector. These codes are also used by the Medicaid program, but they are not payable by Medicare.
- Certain H codes are used by those State Medicaid agencies that are mandated by State law to establish separate codes for identifying mental health services such as alcohol and drug treatment services.
- The T codes are designated for use by Medicaid State agencies to establish codes for items for which there are no permanent national codes and for which codes are necessary to meet a national Medicaid program operating need. T codes are not used by Medicare but can be used by private insurers.

Code Modifiers

In some instances, insurers instruct suppliers that a HCPCS code must be accompanied by code modifier to provide additional information regarding the service or item identified by the HCPCS code. Modifiers are used when the information provided by a HCPCS code descriptor needs to be supplemented to identify specific circumstances that may apply to an item or service. For example, a UE modifier is used when the item identified by a HCPCS code is "used equipment," a NU modifier is used for "new equipment." The level II HCPCS modifiers are either alpha-numeric or two letters.

C. REQUESTING A REVISION TO THE HCPCS LEVEL II CODES

Anyone can submit a request for modifying the HCPCS level II national code set. A document explaining the HCPCS revision process, as well as a detailed format for submitting a request, is available on the HCPCS website at <http://www.cms.hhs.gov/medicare/hcpcs>. Besides the information requested in this format, a requestor should also submit any additional descriptive material, including the manufacturer's product literature and information, that it thinks would be helpful in furthering our understanding of the medical features of the item for which a coding revision is being recommended. The HCPCS coding review process is an ongoing continuous process. Requests may be submitted at any time throughout the year. Requests that are received and complete by January 3 of the current year will be considered for inclusion in the next annual update (January 1st of the following year). Requests received on or after January 3, and requests received earlier that require additional evaluation, will be included in a later HCPCS update. There are three types of coding revisions to the HCPCS that can be requested:

1. That a permanent code be added
When there is not a distinct code that describes a product, a code may be requested (1) if the FDA allows the product to be marketed in the United States and (2) if the product is not a drug, the product has been on the market for at least 3 months; if the product is a drug, there is no requirement to submit marketing data; and (3) the product represents 3 percent or more of the outpatient use for that type of product in the national market. If a request for a new code is approved, the addition of a new HCPCS codes does not mean that the item is necessarily covered by any insurer. Whether an item identified by a new code is covered is determined by the Medicare law, regulations, and medical review policies and not by the assignment of a code.
2. That the language used to describe an existing code be changed
When there is an existing code, a recommendation to modify the code can be made when an interested party believes that the descriptor for the code needs to be modified to provide a better description of the category of products represented by the code.
3. That an existing code be deleted

When an existing code becomes obsolete or is duplicative of another code, a request can be made to delete the code.

When there is no currently existing code to describe a product, a miscellaneous code/not otherwise classified code may be appropriate. The use of a miscellaneous code permits a claims

history to be established for an item that can be used to support the need for a national permanent code.

Requests for coding revisions should be sent to the following:

Alpha-Numeric HCPCS Coordinator,
Center for Medicare Management,
Centers for Medicare and Medicaid Services,
C5-08-27,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

CMS HCPCS Workgroup

The CMS HCPCS Workgroup is an internal workgroup comprised of representatives of the major components of CMS, the Medicaid State agencies, and the SADMERC. The SADMERC represents Medicare program operating needs with input from the four DMERCs which have responsibility for processing Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) claims for the Medicare program. Coding decisions are coordinated with both public and private insurers. The CMS HCPCS workgroup considers each coding request, and beginning with the 2006 cycle, will determine whether HCPCS coding requests warrant a change to the national permanent codes. Prior to the 2006 cycle, the National Panel was responsible for final decisions.

When a recommendation for a revision to the HCPCS is received, it is reviewed at a regularly scheduled meeting of the CMS HCPCS Workgroup. Ordinarily, the CMS HCPCS Workgroup meets monthly to discuss whether coding requests warrant a change to the national permanent codes.

Evaluating HCPCS Coding Requests

The CMS HCPCS workgroup applies the following criteria to determine whether there is a demonstrated need for a new or modified code or the need to remove a code:

1. When an existing code adequately describes the item in a coding request, then no new or modified code is established. An existing code adequately describes an item in a coding request when the existing code describes products with the following:
 - Functions similar to the item in the coding request.
 - No significant therapeutic distinctions from the item in the coding request.
2. When an existing code describes products that are almost the same in function with only minor distinctions from the item in the coding request, the item in the coding request may be grouped with that code and the code descriptor modified to reflect the distinctions.
3. A code is not established for an item that is used only in the inpatient setting or for an item that is not diagnostic or therapeutic in nature.
4. A new or modified code is not established for an item unless the FDA allows the item to be marketed. FDA approval documentation is required to be submitted with the coding request application for all non-drug items. For drugs, FDA approval documentation will be accepted up to March 31 following the application deadline as long as the application is otherwise complete and submitted by the deadline.

5. There must be sufficient claims activity or volume, as evidenced by 3 months of marketing activity for non-drug products, so that the adding of a new or modified code enhances the efficiency of the system and justifies the administrative burden of adding or modifying a code.
6. The determination to remove a code is based on the consideration of whether a code is obsolete (for example, products no longer are used, other more specific codes have been added) or duplicative and no longer useful (for example, new codes are established that better describe items identified by existing codes). In developing its decisions, the HCPCS Workgroup uses the criteria mentioned above. In deciding upon a recommendation, the workgroup does not include cost as a factor.

Opportunity for Public Input/Public Meeting Process for HCPCS

On December 21, 2000, the Congress passed the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), Pub. L. 106-554. Section 531(b) of BIPA mandated that we establish procedures that permit public consultation for coding and payment determinations for new DME under Medicare Part B of title XVIII of the Social Security Act (the Act). As part of HCPCS reform, CMS expanded the public meeting forum to include all public requests as of the 2005-2006 coding cycle. Accordingly, CMS hosts annual public meetings that provide a forum for interested parties to make oral presentations and/or to submit written comments in response to preliminary coding and pricing recommendations for new durable medical equipment that have been submitted using the Healthcare Common Procedure Coding System coding revision process. Agenda items for the meetings will be published in advance of the public meeting on the HCPCS website at <http://www.cms.hhs.gov/medicare/hcpcs>. The agenda will include descriptions of the coding requests, the requestor, and the name of the product or service. This change will provide more opportunities for the public to become aware of coding changes under consideration, as well as opportunities for public input into decision-making.

The HCPCS coordinator schedules meetings with interested parties, at their request, as time permits, to discuss their recommendations regarding possible changes to the HCPCS level II codes. These meetings are held at the Central Office of CMS. In addition to representatives from the CMS HCPCS Workgroup, staff from Medicaid and Medicare coverage, payment and operations are invited to attend these meetings. These meetings are not related to the meetings mandated by section 531(b) of BIPA, they are also not decision making meetings or CMS HCPCS Workgroup meetings.

Final Decisions

The CMS HCPCS Workgroup is responsible for making the final decisions pertaining to additions, deletions, and revisions to the HCPCS codes. The CMS HCPCS Workgroup reviews all requests for coding changes and makes final decisions regarding the annual update to the national codes. The Workgroup sends letters to those who requested coding revisions to inform them of the Workgroup's decision regarding their coding requests. The decision letters include, but may not be limited to, the following types of responses:

1. A change to the national codes has been approved that reflects, completely or in part, your coding request.
2. Your request for a coding revision to this year's update has not been approved because the scope of your request necessitates that additional consideration be given to your request before the CMS HCPCS Workgroup reaches a final decision.
3. Your reported sales volume was insufficient to support your request for a revision to the national codes. To determine whether there is sufficient sales volume to warrant a permanent code, we ask requestors to submit 3 months of the most recent sales volume for non-drug items. There is not a requirement to submit marketing data for drugs.
4. Your request for a new national code has not been approved because there already is an existing permanent or temporary code that describes your product.
5. Your request for a code has not been approved because your product is not used by health care providers for diagnostic or therapeutic purposes.
6. Your request for a code has not been approved because the code you requested is for capital equipment.
7. Your request for a code has not been approved because your product is an integral part of another service and payment for that service includes payment for your product; therefore, your product may not be billed separately to Medicare.
8. Your request for a revision to the language that describes the current code has not been approved because it does not improve the code descriptor.
9. Your request for a new code has not been approved because your product is not primarily medical in nature (for example, generally not useful in the absence of an illness or injury).
10. Your request for a code has not been approved because your product is used exclusively in the inpatient hospital setting.
11. Your request for a code has not been approved because it is inappropriate for inclusion in the HCPCS Level II code set and request should be submitted independently to another coding authority (e.g. AMA for CPT coding, ADA for CDT coding, etc.)

Decision letters also inform the requestors that they may contact the entity in whose jurisdiction a claim is filed for assistance in answering any coding questions. For Medicare, contact the SADMERC. Under contract to CMS, the SADMERC is responsible for providing suppliers and manufacturers with assistance in determining which HCPCS code should be used to describe DMEPOS items for the purpose of billing Medicare. The SADMERC has a toll free helpline for this purpose, (877) 735-1326, which is operational during the hours of 9 AM to 4 PM (EST) For Medicaid, contact the state Medicaid agency. For private insurance, contact the individual insurer. A requestor who is dissatisfied with the final decision may submit a new request asking the CMS HCPCS Workgroup to reconsider and re-evaluate the code request. At that time, the requestor should include new information or additional explanations to support the request.

Reconsideration Process

CMS management is considering pilot-testing, a process by which denied applicants would be allowed an opportunity to have their application reconsidered during the same coding cycle. The

basis for denial will be clearly delineated in a notice to the applicant and provided in a timely fashion. This pilot is expected to be introduced during the 2007 coding cycle.

D. HCPCS Updates

Permanent National Codes

The national codes are updated annually, according to the following schedule:

1. Coding requests have to be received by January 3 of the current year to be considered for the next January 1 update of the subsequent year. This means that completed requests must be received by no later than January 3 of the current year to be considered for inclusion in the January update of the following year unless January 3 falls on a weekend; then the due date is extended to the following Monday.
2. Computer tapes and instructions, that include an updated list of codes and identify which codes have been changed or deleted, are updated and sent to our contractors and Medicaid State agencies at least 60 days in advance of the January 1 implementation date for the annual update. In addition, the CMS HCPCS Workgroup's final decisions on all public requests for changes to the HCPCS coding system will be published on the official HCPCS web site at www.cms.hhs.gov/medicare/hcpcs in November of each year.

Temporary Codes

Temporary codes can be added, changed, or deleted on a quarterly basis. Once established, temporary codes are usually implemented within 90 days, the time needed to prepare and issue implementation instructions and to enter the new code into CMS's and the contractors' computer systems and initiate user education. This time is needed to allow for instructions such as bulletins and newsletters to be sent out to suppliers to provide them with information and assistance regarding the implementation of temporary CMS codes.

HCPCS/Medicare Website

Our website, <http://www.cms.hhs.gov/medicare/hcpcs> lists all of the current HCPCS codes, an alphabetical index of HCPCS codes by type of service or product, and an alphabetical table of drugs for which there are level II codes. The website also includes a list of applications submitted in the current coding cycle. Interested parties can submit comments regarding the agenda items to the CMS HCPCS Workgroup by sending an e-mail to CMS through this website. These comments are included as part of the Workgroup's review as it considers the coding requests.

The newly established temporary codes and effective dates for their use are also posted on the HCPCS website at <http://www.cms.hhs.gov/medicare/hcpcs>. This website enables us to quickly disseminate information on coding requests and decisions.

Code Assignment Following Medicare National Coverage Determination

Pursuant to Sec. 1862 (l) (3) (C) (iv) of the Social Security Act (added by Section 731 (a) of the Medicare Modernization Act), the Centers for Medicare and Medicaid Services (CMS), has developed a process by which the CMS HCPCS Workgroup will identify an appropriate existing code category and/or establish a new code category to describe the item that is the subject of a

National Coverage Determination (NCD). If the item is considered Durable Medical Equipment, Prosthetic, Orthotic or Supply (DMEPOS), the CMS will defer to the Statistical Analysis Durable Medical Equipment Regional Carrier (SADMERC) to determine the appropriate code category. Under contract to the CMS, the SADMERC assigns individual DMEPOS products to HCPCS code categories for the purpose of billing Medicare.

As a matter of meeting on-going Medicare program operating needs, processes have existed for some time by which items and services that are newly covered by Medicare are assigned to a new or existing code category. Effective July 1, 2004, the process outlined below has been used by CMS to comply with the requirements of Sec. 1862 (l).

1. Assignment of an Existing "Temporary" or "Permanent" Code: When the CMS determines that an item is already identified by an existing "temporary" or "permanent" (as described in A and B above) HCPCS code category, but was previously not covered, the CMS will assign the item to the existing code category, and ensure that the coverage indicator assigned to the code category accurately reflects Medicare policy regarding payment for the item. Sec. 731 of the MMA does not require that a new code category or a product specific code be created for an item simply because a new coverage determination was made, without regard to codes available in the existing code set.
2. Assignment of a New "Temporary" or "Permanent" Code: When the CMS determines that a new code category is appropriate, CMS will make every effort to establish, publish, and implement the new code at the time the final coverage determination is made.
3. Assignment of an Unclassified Code: Under certain circumstances, the assignment of an item to an unclassified code may be necessary. A number of unclassified codes already exist under various headings throughout the HCPCS Level II code set. When an item is newly covered, but usage is narrow and the item would be billed infrequently, it may be more of an administrative burden to revise the code set than to use an unclassified code along with other, existing processing methods. When a new "temporary" or "permanent" code is appropriate, but the change cannot be implemented and incorporated into billing and claims processing systems at the time the final NCD decision memorandum is released, an unclassified code may be assigned in the interim, until a new code can be implemented, in order to ensure that claims can be processed for the item. The timing of implementation of new "temporary" or "permanent" codes relative to the date of the coverage determination depends on a variety of factors, some of which are not within the direct control of the code set maintainers, for example:
 - coding alternatives may require extensive research;
 - the timing of the coverage determination may be such that the publication deadline for the next Quarterly Update is missed
 - there is insufficient time between NCD and Quarterly Update to incorporate new codes into new policy and accompanying billing instructions, and into claims processing systems along with any edits needed to operationalize the new code.

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